Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 601, 606, 607, 610, 640, and 660

[Docket Nos. 94N–0066 and 94N–0080]

Review of Regulations for General Biologics and Licensing and for Blood Establishments and Blood Products; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting for interested persons to express their comments regarding the biologics regulations that the agency intends to review (21 CFR parts 600, 601, 606, 607, 610, 640, and 660). In the **Federal Register** of June 3, 1994 (59 FR 28821 and 28822, respectively), FDA issued two documents, ''Review of General Biologics and Licensing Regulations'' (Docket No. 94N–0066) and ''Review of Regulations for Blood Establishments and Blood Products'' (Docket No. 94N–0080), that announced that FDA was intending to review certain biologics regulations and requested public comments regarding those regulations. The comment periods have been extended twice and will close on February 13, 1995. The purpose of the public meeting is to allow additional opportunity for public comment concerning the biologics regulations that the agency is reviewing.

DATES: The public meeting will be held on January 26, 1995, from 1:30 p.m. to 5:30 p.m. Submit written notices of participation and written copies or summaries of oral presentations and the approximate amount of time needed for the presentation by January 19, 1995. Submit written comments regarding the biologics regulations under review by February 13, 1995.

ADDRESSES: The public meeting will be held at the Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD 20857. Submit written notices of participation and written copies or summaries of oral presentations and the approximate amount of time needed for the presentation to Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448 or FAX at 301–443–3874. Submit written comments regarding the review of general biologics and licensing regulations identified with docket number 94N–0066 and written comments regarding the review of regulations for blood establishments and blood products identified with docket number 94N–0080 to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth or Jean M. Olson, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 3, 1994 (59 FR 28821 and 28822 respectively), FDA issued two documents, ''Review of General Biologics and Licensing Regulations'' (Docket No. 94N–0066) and ''Review of Regulations for Blood Establishments and Blood Products'' (Docket No. 94N–0080). The documents announced the agency's intent to review biologics regulations, 21 CFR parts 600, 601, 606, 607, 610, 640, and 660, and requested written comments from the public. Interested persons were given until August 17, 1994, to respond to the documents. In the **Federal Register** of August 17, 1994 (59 FR 42193), FDA extended the comment periods to November 15, 1994, in response to requests to allow for additional time for public comment. In the **Federal Register** of November 14, 1994 (59 FR 56448), FDA extended the comment periods to February 13, 1995, based on requests to hold a public meeting regarding the biologics regulations under review.

The Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America requested a public meeting to allow for the presentation of comments regarding the agency's intent to review the biologics regulations. FDA agrees that a public meeting would be useful, and therefore, is holding a public meeting to allow all interested persons to present their comments. Representatives from the Center for Biologics Evaluation and Research (CBER) will chair the public meeting.

Every effort will be made to accommodate each person who wants to participate in the public meeting. However, each person who wants to ensure his or her participation in the meeting is encouraged, by close of business on January 19, 1995, to: (1) File a written notice of participation containing the name, address, phone number, facsimile number, affiliation, if any, of the participant, topic of the presentation, and approximate amount of time requested for the presentation; and (2) submit a copy or summary of their presentation. The requested information, including the written notice of participation, may be submitted to the contact person (address above).

Before the meeting, CBER will determine the amount of time assigned to each person and the approximate scheduled time for each presentation. A schedule showing the persons making presentations will be filed with the Dockets Management Branch (address above) and mailed or FAX'ed to each participant before the meeting. Interested persons attending the meeting who did not request an opportunity to make a presentation will be given the opportunity to make an oral presentation at the conclusion of the meeting, as time permits.

All public comments received at the public meeting and all written comments submitted to the Dockets Management Branch by February 13, 1995, will be considered in the review of the regulations to determine whether they should be revised, rescinded, or continued without change. After careful review of the public comments, FDA intends to publish a proposed rule to amend those regulations that FDA deems appropriate.

Interested persons may, on or before February 13, 1995, submit written comments regarding the biologics regulations the agency intends to review (21 CFR parts 600, 601, 606, 607, 610,

640, and 660) to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the appropriate docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript of the public meeting and copies of information and comments submitted to the meeting record will be available for examination at the Dockets Management Branch (address above) approximately 15 working days after the meeting, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 4, 1995.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 95–460 Filed 1–4–95; 3:01 pm]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[PS–76–92]; [PS–51–93]

RIN 1545–AR48; RIN 1545–AR93

Recognition of Gain or Loss by Contributing Partner on Distribution of Contributed Property or Other Property

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to the recognition of gain or loss on certain distributions of contributed property by a partnership under section 704(c)(1)(B) of the Internal Revenue Code of 1986 (Code). This document also contains proposed regulations relating to the recognition of gain on certain distributions to a contributing partner under section 737. Changes to the applicable law were made by the Revenue Reconciliation Act of 1989 and the Energy Policy Act of 1992. The proposed regulations affect partnerships and their partners and are necessary to provide guidance for complying with the applicable tax law.

DATES: Written comments must be received by April 10, 1995. Requests to speak (with outlines of oral comments) at a public hearing scheduled for June 19, 1995, at 10 a.m. must be received by May 29, 1995.

ADDRESSES: Send submissions to: CC:DOM:CORP:T:R (PS–76–92; PS–51–93), Room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC. 20044. In the alternative, submissions may be hand delivered between the hours of 8:00 a.m. and 5:00 p.m. to: CC:DOM:CORP:T:R (PS–76–92; PS–51–93), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC. The public hearing has been scheduled to be held in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Stephen J. Coleman, (202) 622–3060; concerning submissions and the hearing, Michael Slaughter, (202) 622–7190 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Introduction

This document proposes to add new §§ 1.704–4, 1.737–1, 1.737–2, 1.737–3, 1.737–4, and 1.737–5 to the Income Tax Regulations (26 CFR part 1) under sections 704(c)(1)(B), 704(c)(2), and 737 of the Code.

Background

Section 704(c)(1)(A) of the Internal Revenue Code (Code) requires that gain or loss with respect to property contributed to a partnership by a partner be shared among the partners so as to take into account any built-in gain or loss in the property at the time of the contribution. Prior to its amendment by the Revenue Reconciliation Act of 1989 (1989 Act), section 704(c) did not require the recognition of built-in gain or loss by a contributing partner on a distribution of contributed property by the partnership. The 1989 Act added sections 704(c)(1)(B) and 704(c)(2) to the Code. Section 704(c)(1)(B) provides that in the case of a distribution of contributed property to another partner within five years of its contribution to the partnership, the contributing partner must recognize gain or loss in an amount equal to the gain or loss the partner would have been allocated under section 704(c)(1)(A) on a sale of the property by the partnership at its fair market value at the time of the distribution. Section 704(c)(2) provides for an exception for distributions of certain like-kind property. The legislative history of the 1989 Act indicates that Congress intended section 704(c)(1)(B) to eliminate the inconsistent treatment of sales and distributions by a partnership and thereby prevent partners from circumventing the rule requiring pre-contribution gain or loss on contributed property to be allocated to the contributing partner by distributing the property to another partner. H.R. Rep. No. 101–247, 101st Cong., 1st Sess. 406 (1989).

Prior to the enactment of the Energy Policy Act of 1992 (1992 Act), a partner who contributed appreciated property to a partnership did not recognize gain on a distribution to the distributee partner of partnership property other than money. The 1992 Act added section 737 to the Code to require a contributing partner to recognize gain to the extent of the lesser of (i) the net precontribution gain on property contributed to the partnership by the partner, or (ii) the excess of the value of the distributed property over the adjusted basis of the partner's interest in the partnership. H.R. Rep. No. 102–1018, 102d Cong., 2d Sess. 428 (1992).

Explanation of Provisions

A. Overview

Section 704(c)(1)(B) generally requires a contributing partner to recognize gain or loss when the property contributed by that partner is distributed to another partner within five years of its contribution to the partnership. Section 737 generally requires a contributing partner to recognize gain when the partner receives, within five years of the contribution, a distribution of other property with a fair market value in excess of the partner's adjusted basis in the partnership. Both sections apply only to distributions made to a partner in the partner's capacity as a partner. Section 704(c)(1)(B) and section 737 do not apply to transactions or distributions in which the partner is not acting in the capacity of a partner (e.g., transactions or distributions subject to section 707(a) or section 751(b)).

The proposed regulations provide rules for determining when section 704(c)(1)(B) and section 737 apply and the amount of gain or loss that must be recognized by the contributing partner under the applicable section. The proposed regulations also provide rules for determining the character of such gain or loss and for making the necessary basis adjustments. The proposed regulations contain several exceptions that are based on the